

ELABORATIONS

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First Annual Exhibition on Waived Testing

by Fran Lehr

Are you a physician office laboratory with a Certificate of Waiver, Provider Performed Microscopy Procedures license, a hospital that performs point-of-care testing, or a moderate complexity physician office laboratory that performs waived testing and would like to increase your testing capability in the category of waived testing? **The First Annual Exhibition on Waived Testing is a meeting just for you.** It will be held on June 21, 2002, at the Shoreline Conference Center located in north Seattle. This exhibition is sponsored by the Washington Public Health Laboratories Training Program in partnership with Region 10 Seattle Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration, HCFA).

Currently the federal government has approved waived test systems for over 50 waived analytes. The analytes include urine dipstick, protime, glucose, cholesterol, HDL, triglyceride, Group A strep, *Helicobacter pylori*, Influenza A&B, urine pregnancy, FSH, Lyme Disease, ovulation tests, etc. A complete listing of analytes for which at least one test kit has been categorized as waived can be found at the following website: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>. A listing of approved waived testing kits can be found at the following website: http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

The Exhibition on Waived Testing includes:

- A two-hour course entitled ***Improving Patient Care: Urine Testing in the Physician Office Laboratory*** open to Certificate of Waiver laboratories only;

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- An **all-day series of lectures** open to all licensed laboratories performing waived testing;
- A **manufacturers' product show** of waived testing systems

Improving Patient Care: Urine Testing in the Physician Office Laboratory: This two-hour course was developed based on results of the pilot studies (see page 3) of Colorado, Iowa, Office of the Inspector General, and Centers for Medicare and Medicaid Services (CMS). The studies indicated that waived laboratories were having difficulty following manufacturer's instructions in addition to having test performance-related problems. The major recommendation from these pilot studies was to provide some type of basic education/training in following manufacturers' instructions and good laboratory practices. This course is designed for the personnel performing waived testing in physician offices and other facility types that hold a Certificate of Waiver (COW) under the Washington Medical Test Site Laboratory Licensure Program or the CLIA program.

The course will focus on reading/interpreting manufacturers' instructions, the parts of a package insert one should pay attention to, understanding good laboratory practice, and performance of the urine dipstick procedure. In addition, a brief discussion regarding rapid Strep A testing will be covered. Participants will have the opportunity to attend a morning session (10:00 am - noon) or an afternoon session (2:00 - 4:00 pm). A certificate of participation and continuing education units will be awarded if you attend the class in addition to attending the manufacturers' product show. Since space and course materials are limited, only testing personnel from Certificate of Waiver facilities will be admitted to the class. If there is overwhelming response from other than COW facilities, the course will be repeated in the future.

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Waived Testing Exhibition, continued from page 1

The all-day series of lectures will be presented by laboratory experts on waived testing. The speakers will cover such topics as Medicare Part B billing and coverage, quality assurance, and other pertinent topics. You will be able to talk with the speakers about your testing issues and concerns during lunch and coffee breaks. (See the box at the bottom of this page for a list of the invited speakers.) The lecture series is open to all registrants of the Exhibition.

The manufacturers' product show is the first of its kind devoted to waived testing systems where you will have the opportunity to see many waived test systems, talk with the manufacturers, and network with laboratory experts as well as personnel from other laboratories performing waived tests. Manufacturers such as Roche Diagnostics, Beckman Coulter, Quidel Corporation, Remel, Cholestech Corporation, Life Sign, Becton Dickinson, Johnson & Johnson, and Bayer Corporation will be exhibiting. Others have been invited and have expressed great interest in participating. Quality assurance programs such as American Proficiency Institute, Idaho Bureau of Laboratories, and COLA will be attending. They are good resources on quality testing.

Continuing education units (CEUs) and a certificate of attendance will be awarded to participants. A total of

0.8 CEUs will be awarded to those attending the all-day session. A total of 0.2 CEUs will be awarded to those attending the two-hour waived testing class only. The CEUs are approved by the California Department of Health Services and may be used towards continuing education requirements.

Who should attend: We encourage testing personnel who perform waived testing, point-of-care testing coordinators, home health agencies, nursing home facilities, emergency medical groups, physicians' offices, public/community health clinics, Indian health services, pharmacies, student health clinics, and other entities involved in performing waived testing to attend.

Fees: Since this exhibition will pilot the two-hour course targeted to Certificate of Waiver (COW) facilities, a subsidized fee of \$25.00 will be charged for these facilities (COW). This fee covers the two-hour course, entry into the exhibition, speakers' session, CEUs, and lunch. Certificate of Waiver facilities will need to indicate their Medical Test Site license or CLIA number on the registration form. All other license types, i.e. PPMP, accredited laboratories, moderate and/or high complexity laboratories, will pay \$50.00. This fee will allow entry into the exhibition, speakers' session, coffee break, CEUs, and a box lunch. A registration form can be found on page 3. Program flyers will be mailed in March.

Nowhere has there been an exhibition of this type dedicated entirely to waived testing. If you want to expand your testing ability in your laboratory, this is your chance to listen and speak with laboratory experts, and see many waived test systems. The two-hour course that will be given at the exhibition is the first course ever to be designed strictly for laboratories that only perform waived testing. See you there on June 21st!

For more information, please call Fran Lehr at (206) 361-2895 or Shelley Lankford at (206) 361-2810.

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Website addresses:

DOH home page: <http://www.doh.wa.gov>

LQA home page:
http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Invited Speakers

Larry Crolla, PhD
Robert Fouty, MD
Linda Windley, Training Leader, Noridian Part B
Judy Yost, MA, Head of the national CLIA program
Panel of experts to be announced

CMS Waived & PPMP Pilot Project Executive Summary

The following article is the executive summary of the Centers for Medicare and Medicaid Services (CMS) Waived and Provider Performed Microscopic Procedure (PPMP) Pilot Project that was done around the United States in 2000-2001. The project consisted of on-site inspections of a random sample of CLIA waived and PPMP labs in selected states.

Expanded pilot studies of waived and PPMP laboratories demonstrate that 50% of laboratories performing waived tests do not follow the manufacturer's instructions or do not have manufacturer's instructions. The only CLIA requirement for waived laboratories is to follow the manufacturer's test instructions. These findings mirror those of previous pilots conducted by Colorado, Ohio, New York and most recently, the Office of the Inspector General (OIG). If these percentages are nationally representative, as many as 60,000 laboratories may not be following manufacturer's instructions and may be performing tests incorrectly to potentially harm patients.

Waived and PPMP laboratories constitute 74% of the total 170,000 CLIA enrolled laboratories and have no direct oversight. In this project, HCFA surveyed 436 facilities that represent 2.5% of the waived and PPMP laboratories in eight states. The surveyors observed quality problems that HCFA would not have discovered without visiting these laboratories.

Specifically, 20% of the waived laboratories were not performing quality control (QC) as required by the manufacturer, and 12% were not performing the additional QC requirements prescribed by CDC as a condition of test waiver. These percentages are artificially low because only certain waived tests require the performance of QC. Particular examples of problems identified by the surveyors include laboratories that were cutting fecal occult blood cards and urine dipsticks in segments to extend their use which altered

the mix of reagent and specimen thereby destroying the credibility of these tests. Other laboratories were using a variety of expired components from different test kits which is prohibited by the manufacturer. One laboratory was using the wrong software for a popular cholesterol instrument. When surveyors explained the potential accuracy problems resulting from these activities, the facilities were eager to change. Most facilities wanted to "do the right thing" but had no resources or training to do so.

PPMP laboratories must meet the same CLIA quality standards as laboratories performing moderate complexity tests. This project found that 25% of the PPMP laboratories do not document personnel competency, and 38% do not evaluate test accuracy at least twice yearly. Also 6% percent of the waived and 6% of the PPMP laboratories had inappropriate certificates; these laboratories were conducting tests they were not authorized to perform. Additional findings are that states with laboratory licensure programs had at least five times fewer problems than states with no program. Doctors and nurses perform most of the tests. Lastly, not following instructions is exacerbated by lack of training of testing personnel and creates an extremely hazardous combination for test accuracy. HCFA confirmed that lack of routine oversight in waived and PPMP laboratories continues to be a significant challenge to ensuring quality testing.

Based on the findings, the following recommendations were made: Institute an educational program for waived and PPMP laboratories; validate the effectiveness of this educational program; survey a percentage of waived and PPMP laboratories annually; develop a self assessment tool for PPMP laboratories; provide educational material as part of the CLIA enrollment process; have State Survey Agencies contact waived and PPMP laboratories to verify test menus.

First Annual Exhibition on Waived Testing Registration Form

Public Health Laboratories Training Program

1610 NE 150th Street * PO Box 550501

Shoreline, WA 98155-9701

Name: _____ Day Phone: _____

Organization: _____ Email: _____

Work Address: _____ State: _____ Zip: _____

☐ **Category I:** Certificate of Waiver (COW) Facilities \$25.00 (subsidized) MTS/ CLIA #: _____

C.O.W. Training Series Module 1: *Improving Patient Care: Urine Testing in the Physician Office Laboratory*

Class time Preference (circle one) 10: 00 AM or 2:00 PM

☐ **Category II:** PPMP, Accredited Facilities and all other certificates \$50.00

HOW TO REGISTER: Complete the registration form and mail to the Department of Health, PHL Training Program or FAX to: (206) 361-2904. A confirmation packet will be sent to you by mail. The packet will contain your registration confirmation, payment instructions and a map to the Exhibition location. **Please do not send money with your registration form.** **REGISTRATION DEADLINE : May 21, 2002**

Waived Testing Helpful Hints

A self-study PowerPoint presentation on Good Laboratory Practices can be found on the following website:

http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Select the sidebar "Updates"

Select "Good Laboratory Practices with Waived Test Systems"

NOTE: You do not need to have the Microsoft PowerPoint software loaded on your system to view this document.

Calendar of Events

PHL Training Classes:

Advanced Hematology	
April 2	Shoreline
April 3	Shoreline
Waived Testing Exhibition	
June 21	Shoreline

WSSCLS/NWSSAMT Spring Meeting

April 25-27 Everett

Northwest Medical Laboratory Symposium

October 16 - 19 Portland

9th Annual Clinical Laboratory Conference

November 11 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.